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10/533,749	05/10/2005	Lawrence Allan Lynn		7983

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,749	LYNN, LAWRENCE ALLAN	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4 2008 has been entered.

Specification

2. The amendment filed May 23 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to the specification at the end of paragraph [042] and in the middle of paragraph [0043] are considered to be new matter as they are not supported by the specification and/or claims as originally filed. Specifically, the steps of reducing the internal volume of the extension tube after a first delay, a second delay, and a third delay where the first residual volume is less than initial volume and the second residual volume is less than the first residual volume do not have support in the original disclosure. Also, the sequential reducing of volume every 24 hours up to three times for

maintaining the patency of an indwelling catheter over a 24-72 hour period does not have support in the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose a volume reduction system comprised of at least one of a plurality of volume reducers, a single volume reducer having a plurality of levels of reduction, and a single volume reducer comprised of a plurality of multiple elements. Even though there appears to be support for the language of "a plurality of levels of reduction, and a single volume reducer comprised of a plurality of multiple elements", there is no disclosure of "a volume reduction system". It is suggested that the specification and/or claims be amended such that the language of the claims with regards to the volume reduction system corresponds with the language used in the specification.

Claim Objections

4. Claims 5, 11-16, 18, 23-26, 30, and 31 are objected to because of the following informalities: In line 2 of claim 5, there appears to be a word missing after "system". In claim 18, it is unclear if the "at least one element" in lines 2-3 is referring to the "at least one volume reducing element" in line 13 of claim 8 or a different at least one element. In claim 11, it is unclear if the reducers are a single clamp or if each reducer is a clamp. In claim 30, it is unclear if the "at least one terminal" in line 9 is referring to the "at least

one proximal terminal" in lines 7-8 of claim 30 or a different at least one terminal. There appears to be a punctuation error in the phrase "beneath the skin of a patient the lumen extending into a blood vessel" in line 4 of claim 31. Claim 11 and 12 recite the limitation "the reducers" in line 1. Claim 13 recites the limitation "the elements" in line 1. Claim 14-16 recite the limitation "the clamps" in line 1. Claim 23-26 recite the limitation "the volume reducers" in line 1. There is insufficient antecedent basis for these limitations in these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19-26 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The medical device having at least one volume reducer which is configured to reduce the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and prior to refilling of the extension tube, at least one volume reducer is further configured to reduce the volume of the single extension tube a second time to define a second

residual volume of the extension tube where the second residual volume of the extension tube is less than the first residual volume of the extension tube does not have support in the original disclosure. Also, the steps of progressively reducing comprising reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and reducing the volume of the single extension tube a second time to define a second residual volume of the extension tube where the second residual volume of the extension tube is less than the first residual volume of the extension tube does not have support in the original disclosure. The steps of sequentially reducing comprising reducing the volume of the single extension tube a first time, to define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to define a second residual volume of the extension tube where the second residual volume of the extension tube is less than the first residual volume of the extension tube does not have support in the original disclosure. Also, the steps of reducing the internal volume of the extension tube a first time, a second time, and a third time, after a first, a second, and a third delay of at least several hours, respectively, where a first, a second, and a third residual fluid volume is defined, respectively, and where the first residual volume is less than an initial volume, the second residual volume is less than the first residual volume, and the third residual volume is less than the second residual volume do not have support in the original disclosure. The method of maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period also do not have support in the original disclosure.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-26, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear if "the system" in line 15 is in reference to the catheter-flushing system in line 1, the patient mounted tubing system in line 4, or the at least one volume reduction system in line 12. In claim 8, it is unclear which volume reducer from the plurality of volume reducers is being referred to with regards to the use of "the volume reducer" in line 14. In claim 19, it is unclear if the "at least one volume reducer" in line 17 refers to the same at least one volume reducer recited in lines 14-15 or if another at least one volume reducer is being recited. In claim 20, it is unclear which volume reducers from the plurality of volume reducers recited in line 12 of claim 19 are being referred to with regards to the use of "the volume reducers" in line 1. In claim 28, it is unclear which volume reducer from the plurality of volume reducers recited in line 11 of claim 27 is being referred to with regards to the use of "the volume reducer" in line 1. In claim 29, it is unclear which volume reducer from the plurality of volume reducers recited in line 12 of claim 29 is being referred to with regards to the use of "the volume reducer" in line 15. Also, in claim 29, it is unclear if the "at least one volume reducer" in lines 20-21 refers to the same at least one volume reducer recited in line 18 or if another at least one volume reducer is being recited.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (U.S. Patent No. 6,958,049) in view of Bierman (U.S. Patent No. 5,318,546). Ash discloses a catheter-flushing system having a tubing system comprising a single extension tube (14) and a volume reduction system (20). The single extension tube (14) is in fluid connection with an indwelling portion of a catheter (10). In lines 9-28 of column 6, Ash discloses that the tubing system or catheters can include single or double lumens. The tubing system defines an internal volume and at least one proximal terminal including a seal (28). The proximal terminal has intermittent connection with an external fluid source or a flush solution such as saline (lines 14-16 of column 5) or a mixture of a diluent and at least one of an anticoagulant and an antimicrobial agent (lines 25-36 of column 7). Activation of the volume reducer is capable of reducing the volume within the tubing system by a plurality of discrete volumes. Ash discloses the system substantially as claimed. However, Ash is silent on the catheter-flushing system having at least one volume reduction comprised of at least one of a plurality of volume reducers, a single volume reducer having a plurality of levels of reduction, and a single volume reducer comprised of a plurality of multiple elements. Bierman discloses a single extension tube (18) with a volume reduction system comprised of a plurality of

volume reducers (20) or a single volume reducer (22) having a plurality of levels of reduction (42) or a single volume reducer (22) having a plurality of multiple elements or clamps (20) where the volume reduction system is used to control fluid flow in the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reduction system of Ash with the volume reduction system as taught by Bierman as a mere substitution of one type of volume reduction system and also because the reduction system of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claim 8, the patient mounted system includes a single extension tube (14) having a distal end connectable to a catheter (10), an internal open space defining a variable internal volume, and a lumen extending through the tube. The volume reducer comprises at least one volume reducing element (20) mounted within the system where the element comprise a clamp. The volume reducer can be considered to be a pinch clamp and also defines opposing elongated opposing surfaces. The tube (14) has a variable internal diameter (see lines 16-18 of column 6) and includes an enlarged portion as seen in Figure 1. Ash discloses the system substantially as claimed. However, Ash is silent on the system having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers comprising of volume reducing elements or clamps(20) which are used to control fluid flow in the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for

better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claim 19, the medical device comprises a fluid-lock system with a distal portion which defines an indwelling portion and a single extension tube (14) having an internal space defining an internal volume. The medical device also has a volume reducer (20) for engaging the system and for progressively reducing the volume of flush solution contained within the internal space by facilitating movement of at least sequential portions of the flush solution into a blood vessel. Ash discloses the system substantially as claimed. However, Ash is silent on the medical device having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers (20) which are used to control fluid flow in the tube. At least one volume reducer is configured to reduce the volume of the single extension tube a first time and at least one other volume reducer is configured to reduce the volume a second time such that the second residual volume is less than the first residual volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claims 27 and 29, the system includes a reservoir comprising a single extension tube (14) and a volume reducer (20) configured for engaging sequential portions of the reservoir. Ash discloses the system substantially as claimed. However, Ash is silent on the system having a plurality of volume reducers. Bierman discloses a single extension tube (18) with a plurality of volume reducers (20) which are used to

control fluid flow in the tube. At least one volume reducer is configured to reduce the volume of the single extension tube a first time and at least one other volume reducer is configured to reduce the volume a second time such that the second residual volume is less than the first residual volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman as the plurality of volume reducers of Bierman allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

As to claim 30, Ash discloses disposing the tubing system comprising a single extension tube (14) in fluid connection with an indwelling portion of a catheter (10), flowing flush solution from an external fluid source, sealing the proximal terminal of the tubing system, and progressively reducing the internal volume of the tubing system through the use of a volume reducer. As to claim 31, Ash discloses disposing a single extension tube (14) in fluid connection with an indwelling portion of a catheter (10), flowing flush solution from an external fluid source, sealing the proximal terminal of the tubing system, and sequentially reducing the internal volume of the extension tube a plurality of different times to displace sequential portions of the residual volume of the flush solution into the lumen through the use of a volume reducer (line 61 of column 4 to line 21 of column 5 and lines 45-62 of column 5). As to claims 32-34, Ash also discloses first, second, and third delays of at least several hours where after each delay, the internal volume of the extension tube is reduced to force flush solution distally out of the extension tube and along the lumen (line 61 of column 4 to line 21 of column 5 and

lines 45-62 of column 5). As to claims 35 and 36, Ash discloses a method for maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period where the internal volume of the extension tube is reduced a plurality of times to express sequential portions of the flush solution from the extension tube into the lumen to sequentially flush the lumen at a plurality of different times (line 61 of column 4 to line 21 of column 5 and lines 45-62 of column 5). Ash discloses the method substantially as claimed. However, Ash is silent on the steps of progressively or sequentially reducing comprising reducing the volume of the single extension tube a first time and reducing the volume a second time such that the second residual volume is less than the first residual volume. Bierman discloses a method of flushing a lumen where the volume of the single extension tube is reduced a first time and a second time such that the second residual volume is less than the first residual volume which are used to control fluid flow in the tube. Bierman discloses at least one volume reducer which is configured to reduce the volume of the single extension tube a first time and at least one other volume reducer is configured to reduce the volume a second time such that the second residual volume is less than the first residual volume. Also, Bierman discloses a plurality of levels of reduction (42) such that a first, second, and third residual volume can be defined. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the plurality of volume reducers as taught by Bierman to allow for the steps of progressively and sequentially reducing the volumes in the tube as this allows for better control of the fluid flow in the tube (lines 29-47 of column 10).

Response to Arguments

11. Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

12. The terminal disclaimer filed on May 23 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,689,109 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
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